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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,520	01/21/2004	David L Freed	1001.2489101	1095
11050	7590	01/13/2011		
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			ART UNIT	PAPER NUMBER
			3779	
			MAIL DATE	DELIVERY MODE
			01/13/2011 PAPER	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID I. FREED

Appeal 2009-009625
Application 10/760,520
Technology Center 3700

Before: LINDA E. HORNER, MICHAEL W. O'NEILL, and
FRED A. SILVERBERG, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL¹

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

David I. Freed (Appellant) seeks our review under 35 U.S.C. § 134 of the Examiner's decision rejecting claims 1-7, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, 69-75, 81, 82, 87-89, 93, and 97-102.² Claims 19-21, 23-27, 41, 42, 57, 68, 76-80, 83-86, 90-92, and 94-96 are withdrawn from consideration.³ Claims 8, 9, 22, 38, 54, 55, and 65 are cancelled. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

THE INVENTION

Appellant's claimed invention is "an endoscopic device that combines tissue cutting and spraying in a single device for use in, for example, a colonoscopic polypectomy." Spec. para. [001]. Claim 1 is reproduced below.

1. A medical device comprising:
a proximal handle;
an elongated member having a proximal end, a distal end, and a lumen therebetween, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body;

² Appellant requests allowance of the rejected claims. App. Br. 33. We treat such a request for allowance as a request to reverse the rejection.

³ Appellant requests allowance of the withdrawn claims (App. Br. 6, 33); however, the withdrawn claims are not before us because the Board reviews adverse decisions of the Examiner and the withdrawn claims were not rejected in the Office Action that is the subject of this appeal. *See* 35 U.S.C. § 6(b); see also Office Action dated September 5, 2007.

an end effector consisting essentially of a snare loop proximate the distal end of the elongated member, actuation of the proximal handle causing the snare loop to sever tissue; and

a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member.

THE REJECTIONS

Appellant seeks review of the following rejections:

1. Rejection of claims 1-4, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, and 97-100 under 35 U.S.C. § 103(a) as being unpatentable over Konomura (US 4,682,599, issued July 28, 1987) and Levinson (US 6,660,011 B2, issued December 9, 2003).
2. Rejection of claims 5-7 under 35 U.S.C. § 103(a) as being unpatentable over Konomura, Levinson, and McAlister (US 5,599,324, issued February 4, 1997).
3. Rejection of claims 69-75, 81, 82, 89, 93, and 101 under 35 U.S.C. § 103(a) as being unpatentable over Konomura, Levinson, and Okada (US 5,871,440, issued February 16, 1999).
4. Rejection of claims 87, 88, and 102 under 35 U.S.C. § 103(a) as being unpatentable over Konomura, Levinson, and Termanini (US 4,204,528, issued May 27, 1980).

ISSUES

The issues presented by this appeal are:

Would the disclosures of Konomura and Levinson have led a person of ordinary skill in the art to “an end effector consisting essentially of a snare loop” as called for in independent claims 1, 34, 47, and 59?

Did the Examiner articulate a sufficient reason with rational underpinning to explain why a person having ordinary skill in the art would have been led to modify the flow path of Konomura in light of the teaching of Okada so that a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path, to arrive at the invention of claims 69, 89, and 93?

Did the Examiner articulate a sufficient reason with rational underpinning to explain why a person having ordinary skill in the art would have been led to modify the flow path of Konomura in light of the teaching of Termanini so that “the flow path comprises an inlet and a plurality of outlets connecting to the inlet,” to arrive at the invention of claim 87?

ANALYSIS

Rejection of claims 1-4, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, and 97-100 under 35 U.S.C. § 103(a) as being unpatentable over Konomura and Levinson

Independent claims 1 and 34 are each directed to a medical device that includes an end effector “consisting essentially of a snare loop” that severs tissue when actuated. Similarly, independent claims 47 and 59 are method claims that include the steps of actuating an end effector “consisting

essentially of a snare loop” to sever tissue of a tissue tract. Appellant’s Specification describes that the endoscopic device 10 includes an end effector such as snare loop 40. Spec. para. [024]; figs. 1, 2, 5, 6.

Appellant’s Specification consistently describes that the endoscopic device combines the ability to sever tissue (e.g., perform a polypectomy) and enable flow communication between the lumen and the outside of the lumen (dye spraying) in a single device. *See, e.g.*, Spec. paras. [005], [040], [041], and [047]. Appellant’s Specification does not describe the endoscopic device performing other functions (e.g., retrieving severed tissue). Spec. *passim*.

The Examiner’s conclusion of obviousness is based on the claim interpretation that “an end effector *consisting essentially of* a snare loop” is equivalent to “an end effector *comprising* a snare loop.” Ans. 10 (citing MPEP § 2111.03, 8th ed., rev. 8, July 2008). We cannot agree with this claim construction. Because claims 1, 34, 47, and 59 call for an end effector “consisting essentially of a snare loop,” the actual structure of the end effector is limited to the claimed snare loop, as well as those additional elements that “do not materially affect the basic and novel properties of the invention.” *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). “[A]ppellant has the burden of showing the basic or novel characteristics of [the claimed invention].” *See In re De Lajarte*, 337 F.2d 870, 874 (CCPA 1964).

Appellant argues that it is a basic and novel characteristic of the claimed device to enable flow communication between the lumen and the outside of the elongated member (“spraying fluid”), and that the end effector

is only a snare loop operated by a single control member so that the flow through the lumen and to the nozzle (50) is not inhibited. App. Br. 14-15; Reply Br. 3.

Independent claims 1 and 34 call for the distal member (or nozzle) to define a flow path that enables a flow communication between the lumen of the elongated member and the outside of the elongated member. Similarly, method claims 47 and 59 call for a nozzle (or distal member) to define a flow path permitting fluid communication between the lumen and the outside of the lumen (or the outside of the elongated member). Consequently, we agree with Appellant that it is a basic and novel characteristic of the claimed device for the flow path to permit fluid communication between the lumen and the outside of the lumen (or the outside of the elongated member).

We interpret claims 1, 34, 47, and 59 to call for an end effector that consists of a snare loop and only those components that do not materially affect fluid communication between the lumen and the outside of the lumen.

The Examiner found that Konomura discloses an end effector (basket 3 comprised of wires 6) for holding or fracturing a foreign matter, but that Konomura is silent regarding an end effector that severs tissue when actuated. Ans. 4-5. The Examiner found that Levinson discloses an end effector that severs tissue when actuated (second set of wires 28). Ans. 5. The Examiner concluded that it would have been obvious “to have a tissue cutting end effector in the apparatus of Konomura to selectively capture, cut

and/or retrieve polyps and other aggregates of organic tissue from a patient's internal organs as taught by Levinson." *Id.*

It is unclear to us from the wording the Examiner chose to articulate the rejection as to whether the Examiner is proposing to add Levinson's end effector (second set of wires 28) to Konomura's end effector (basket 3 comprised of wires 6) or to substitute one for the other. Given that Levinson discloses that a snare loop (e.g., second set of wires 28) has no ability to capture or retrieve an excised lesion (Levinson, col. 1, ll. 32-35), and that the Examiner concludes the proposed combination is capable of retrieving polyps, we conclude that the proposed combination intends to add Levinson's end effector (second set of wires 28) to Konomura's end effector (basket 3 comprised of wires 6).

The Examiner's finding that the combined Levinson and Konomura end effector is an end effector consisting essentially of a snare loop, as called for in independent claims 1, 34, 47, and 59, fails to address the requirement in the claims that elements other than the snare loop that are included in the end effector may not materially affect fluid communication between the lumen and the outside of the lumen. Appellant argues that the combined end effector of Konomura and Levinson would inhibit the basic and novel characteristic of the claimed device for the flow path to permit fluid communication between the lumen and the outside of the lumen. App. Br. 16-19. Given that the proposed combination increases the elements in the flow path through the lumen, and the absence of a finding on this issue

by the Examiner, we cannot conclude that the proposed combination meets the contested claim limitation by a preponderance of the evidence.

Rejection of claims 5-7 under 35 U.S.C. § 103(a) as being unpatentable over Konomura, Levinson, and McAlister

Claims 5-7 depend indirectly from claim 1. The Examiner's rejection of claims 5-7 uses the same end effector as explained in the analysis of the first rejection *supra*. The additional proposed modification as taught by McAlister is unrelated to the end effector. Consequently, we cannot sustain the rejection of claims 5-7 as it suffers from the same shortcoming as the rejection of independent claim 1 *supra*.

Rejection of claims 69-75, 81, 82, 89, 93, and 101 under 35 U.S.C. § 103(a) as being unpatentable over Konomura, Levinson, and Okada

Independent claim 69 is directed to a medical device that includes a distal member having a flow path wherein at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path. Claim 89 depends from independent claim 47, and claim 93 depends from independent claim 59. Claims 89 and 93, like independent claim 69, each contain the limitation that the distal member has a flow path wherein at least a portion of the flow path has a cross-sectional flow area smaller than both a cross-sectional flow area of an inlet of the flow path and a cross-sectional flow area of an outlet of the flow path.

Appellant argues that the Examiner did not provide a sufficient reason to combine the references as proposed. App. Br. 25-27. We agree.

Okada discloses a twenty-first embodiment of a video endoscopic system 301 that comprises a video endoscope 302 that includes a washing nozzle 372 mounted on the rounded distal end 371. Okada, col. 20, ll. 20-21; col. 22, ll. 56-65; fig. 30B. Okada's washing nozzle 372 is bent to provide cleaning fluid to the foremost lens 328a of the observation lens unit 322 of the video endoscope 302. Okada, col. 22, l. 66 – col. 23, l. 4; figs. 30A, 30B. Okada makes no disclosure relating to the control, accuracy, or efficiency of fluid provided by washing nozzle 372. Okada, *passim*. Thus, we fail to find a rational underpinning for the Examiner's conclusion that use of Okada's washing nozzle 372 would provide greater control over the outlet flow path, or greater accuracy and efficiency when delivering fluids. *See* Ans. 9, 11-12.

Consequently, we cannot sustain the rejection of independent claim 69 or of dependent claims 89 and 93. Further, we also cannot sustain the rejection of claims 70-75, 81, 82, and 101, which depend from independent claim 69, as their rejection suffers from the same shortcoming.

Rejection of claims 87, 88, and 102 under 35 U.S.C. § 103(a) as being unpatentable over Konomura, Levinson, and Termanini

Independent claim 87 is directed to a medical device including a distal member that defines a flow path comprising an inlet and a plurality of outlets connecting to the inlet.

Appellant argues that the Examiner did not provide a sufficient reason to combine the references as proposed. App. Br. 29-31. We agree.

Termanini discloses “a fiber-optic catheter system . . . adapted for visual inspection of the intra-cardiovascular system” that injects clear solution into the bloodstream to reduce the opacity of the blood in order to improve visibility. Termanini, col. 1, ll. 38-57. Termanini discloses that the clear solution is injected into the bloodstream from the apertures 40 of head 36. Termanini, col. 4, ll. 38-39; figs. 1, 3, 6. Termanini discloses that a single aperture 40 may be employed. Termanini, col. 3, ll. 41-44. Termanini makes no disclosure related to the control over the output of fluid provided by the apertures 40 of head 36. Termanini, *passim*. Thus, we fail to find a rational underpinning for the Examiner’s conclusion that use of Termanini’s head 36 having aperture(s) 40 provides “greater control over the outputted flow of fluid.” *See* Ans. 10.

We therefore cannot sustain the rejection of independent claim 87. Further, we cannot sustain the rejection of claims 88 and 102, which depend from independent claim 87, as their rejection suffers from the same shortcoming.

CONCLUSIONS

The disclosures of Konomura and Levinson would not have led a person of ordinary skill in the art to an end effector consisting essentially of a snare loop as called for in independent claims 1, 34, 47, and 59.

The Examiner did not articulate a sufficient reason with rational underpinning to explain why a person having ordinary skill in the art would have been led to modify the flow path of Konomura in light of the teaching of Okada so that a portion of the flow path has a cross-sectional flow area

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smaller than both a cross-sectional flow area of an inlet and a cross-sectional flow area of an outlet of the flow path, to arrive at the invention of claims 69, 89, and 93.

The Examiner did not articulate a sufficient reason with rational underpinning to explain why a person having ordinary skill in the art would have been led to modify the flow path of Konomura in light of the teaching of Termanini so that the flow path comprises an inlet and a plurality of outlets connecting to the inlet, to arrive at the invention of claim 87.

DECISION

We REVERSE the Examiner's decision to reject claims 1-7, 10-18, 28-37, 39, 40, 43-53, 56, 58-64, 66, 67, 69-75, 81, 82, 87-89, 93, and 97-102.

REVERSED

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